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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,694	04/09/2004	William Alejandro Thompson	P25130	8732
7055 7590 03/26/2008 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191				
EXAMINER				
GHALL, ISIS A D				
ART UNIT		PAPER NUMBER		
1611				
NOTIFICATION DATE		DELIVERY MODE		
03/26/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary**Application No.**

10/820,694

Applicant(s)THOMPSON, WILLIAM
ALEJANDRO**Examiner**

Isis A. Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-17, 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 07/09/2004
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The receipt is acknowledged of applicant's election filed 12/19/2007; and IDS filed 07/09/2004.

Claims 1-20 are pending.

Election/Restrictions

1. Applicant's election with traverse of invention III, and species tablet, claims 18-19, in the reply filed on 12/19/2007 is acknowledged. During the telephone interview with Mr. Myers-Payne held on 02/29/2008 the examiner was informed that species election in sections 7-10 was unintentionally overlooked. Accordingly, the following species election was made: isopropyl myristate, ibuprofen, sodium bicarbonate, and citric acid. This species election is made of record, however, such species are subspecies of the transdermal formulation other than tablet (claim 20) that is non-elected. The traversal is on the ground(s) that all the claims can be searched without serious burden since the subject matter of group III overlaps the subject matter of groups I and II. This is not found persuasive because the search system and the focus of the invention are completely different, requiring an undue burden on the patent examiner since the prior art that anticipates group I or II may not anticipate group III. While searches may seem to be overlapping however extensive since the patent

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examiner searches the databases mostly literally. Rarely do applicants present claims to an inventions where the distinctness of the invention are readily clear such as a chemical compound and a gene sequence. It is the responsibility of the examiner to enforce 35 USC 101, which allows the applicant to obtain a patent for a single invention. In the opinion of the examiner the applicants present three distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-17 and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/19/2007.

Claims 18 and 19 are included in the prosecution.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by US 5,527,832 (832).

US '832 disclosed anti-inflammatory and analgesic transdermal gel comprising ibuprofen and permeation enhancer including myristic acid (abstract; col.1, lines 23-25; col.2, lines 12-15, 39-40, examples). The gel is administered once every 24 hour to provide analgesic activity (col.6, lines 59-68).

5. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by US 5,780,047 ('047).

US '047 disclosed patch applied to the skin to provide topical excellent effects of relieving pain and stiffness (abstract; col.2, lines 14-25; col.11, lines 34-38). The patch comprises active ingredient including anti-inflammatory agents and permeation enhancer including myristic acid (col.6, line 61; col.7, lines 39-52; col.8, lines 15-16; col.10, line 34). Administration of the patch at least once every 24 hr is inherent for any medicinal application.

6. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by US 5,976,566 ('566).

US '566 disclosed percutaneous preparation comprising ibuprofen and enhancer given once daily (example 1, col. 9 and 10). Ibuprofen is inherently anti-inflammatory analgesic drug that treat inflammation and pain.

7. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by US 6,083,996 ('996).

US '966 disclosed topical formulation for NSAID delivery for management of pain comprising the drug and permeation enhancer including isopropyl myristate (abstract; col.1, lines 10-14; col.2, lines 1-5; col.4, lines 1-60; col.6, lines 47-49, examples). Tables 6 and 9 show the NSAID is delivered once/24 hr.

8. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by US 2001/0036489 ('489).

US '489 disclosed treating rheumatoid arthritis and osteo-arthritis using topical bathing composition comprising anti-inflammatory agent including ibuprofen for at least once a day (paragraphs 0094-0101; 0140). The composition comprises oils, polyethylene glycol and surfactant (paragraphs 0154-0159), that are inherently increases the skin permeation of the drugs.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US '5,780,047 ('047), US 5,342,535 ('535), US 2001/0036489 ('489) and US 6,083,996 ('996).

US '047 teaches patch applied to the skin to provide topical excellent effects of relieving pain and stiffness (abstract; col.2, lines 14-25; col.11, lines 34-38). The patch comprises active ingredient including anti-inflammatory agents and permeation enhancer including myristic acid (col.6, line 61; col.7, lines 39-52; col.8, lines 15-16; col.10, line 34). The patch further comprises sodium bicarbonate and citric acid (col. 7, lines 10-15). The reference teaches that the patch can be poured or dissolved in bathwater followed by bathing (col.11, lines 12-14), and it is expected that when the patch comprising sodium bicarbonate is poured or dissolved in water will form effervescent because compounds and their properties are inseparable. The patch disclosed by the reference reads on table since it comprises the ingredients of the claimed tablet and used for the same purpose as desired by applicant.

Although US '047 teaches the elements of claim 19, however, the reference does not teach the amount of different ingredients as claimed by claim 19. US '047 does not explicitly teach the patch as tablet. Although US '047 teaches anti-inflammatory agent in the disclosed patch and myristic acid, however, does not explicitly teach ibuprofen and isopropyl myristate.

US '535 teaches effervescent tablet formulated to include active agent such as analgesic soaks to provide therapeutic effect in contact with the user skin (col.3, lines 36-43; col.4, lines 61-68). The effervescent bath tablet comprises 36.99% by weight sodium bicarbonate, 37.15% by weight citric acid (example 2 at col.5).

US '489 teaches treating rheumatoid arthritis and osteo-arthritis using bathing composition comprising anti-inflammatory agent including ibuprofen for at least once a

day (paragraphs 0094-0101; 0140). The composition may comprise sodium bicarbonate and citric acid (paragraph 0126).

US '996 teaches topical formulation for NSAID delivery for management of pain comprising the drug and permeation enhancer including isopropyl myristate (abstract; col.1, lines 10-14; col.2, lines 1-5; col.4, lines 1-60; col.6, lines 47-49, examples). Example 27 at col.17 shows the composition comprising 5% ibuprofen and 5% isopropyl myristate.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide product that can be poured or dissolved in bathwater to relieve pain and stiffness and comprises anti-inflammatory agents, permeation enhancer, sodium bicarbonate and citric acid as disclosed by US '047, and deliver the ingredients in an effervescent tablet comprises specific amounts of sodium bicarbonate and citric acid as disclosed by US '535 because US '535 teaches that such effervescent tablet is formulated as analgesic soaks to provide therapeutic effect in contact with the user skin, and further add ibuprofen to the effervescent tablet forming the analgesic soak as disclosed by US '489 because US '489 disclosed that arthritis pain can be treated by ibuprofen included in the bathwater, and further one having ordinary skill in the art would adjust the amount of the ibuprofen to form 5% by weight of the tablet and replace the myristic acid with 5% isopropyl myristate because US '996 teaches such combination and amounts are preferred for topical delivery and pain management, with reasonable expectation of having effervescent tablet comprising 5% ibuprofen, 5%

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isopropyl myristate, 36.99% by weight sodium bicarbonate, 37.15% by weight citric acid that treat pain from different causes effectively when applied in bathwater.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611

